Remarks

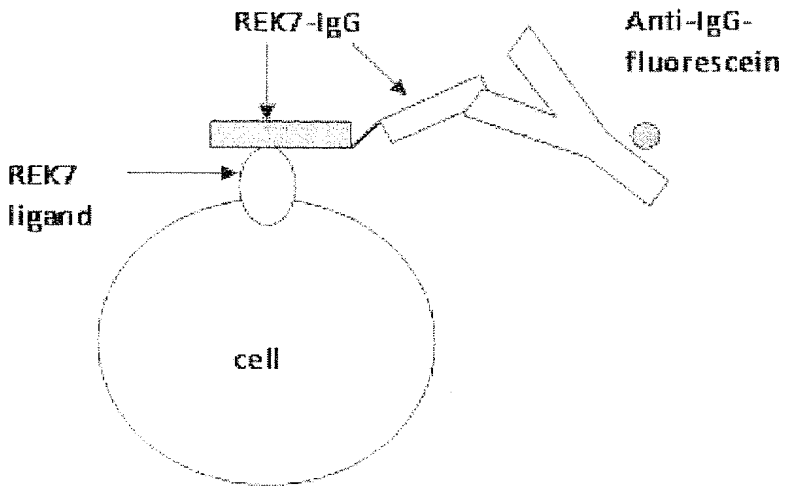
Applicant appreciates the examination of the present application as evidenced by the final Office Action dated September 17, 2009 (hereinafter, the "Final Action"). Applicant further appreciates the Examiner's withdrawal of the rejections under 35 U.S.C. § 102(b) in view of WO 98/44350 to Blau et al.; 35 U.S.C. § 102(e) in view of U.S. Patent Application Publication No. 20030091975 to Leyland-Jones et al.; 35 U.S.C. § 102(b) in view of U.S. Patent No. 4,521,521 to Abbott et al.; 35 U.S.C. § 102(e) in view of U.S. Patent Application Publication No. 20040137425 to Upmeier et al.; and 35 U.S.C. § 102(b) in view of U.S. Patent Application Publication No. 20020107640 to Ideker et al.

Claims 30-52, 54 and 57 are pending in the present application. Applicant respectfully submits that these claims are patentable for at least the reasons below. In the event that the Examiner does not allow the present application, Applicant respectfully requests the courtesy of a telephone interview to advance the prosecution of the application.

I. Claim Rejection Under 35 U.S.C. § 102

Claim 57 stands rejected as being anticipated by U.S. Patent No. 5,798,448 to Caras et al. (hereinafter, "Caras et al."). Applicant respectfully disagrees.

The present invention is distinct from that of Caras et al. in a number of aspects, and in particular and importantly, that the **non-reactive** scaffold of the present invention is **not** analogous to the "scaffold" of Caras as suggested by the Final Action. In contrast, the Caras et al. scaffold is an **intimate and active component of the invention**. To explain further, the REK7-IgG fusion does not represent an example of a construct containing an active binding moiety and a non-reactive scaffold material. As disclosed in Caras et al., **both** parts of the REK7-IgG molecule are "active" or "reactive". Applicant specifically directs the Examiner's attention to the examples, and in particular, example 4 where it is noted that the detection of a REK7 ligand on mammalian cells is performed using the REK7-IgG fusion product. While REK7 binds to the ligand (presumably), the IgG moiety is used to create the detectable signal of REK7-IgG adherence to a ligand on the cell surface as shown in the schematic below.



This adherence is detected by the binding of fluorescently labelled anti-IgG molecules to the IgG portion of REK7-IgG. Applicant notes that, in the present invention, the non-reactive scaffold is non-reactive during the execution of the invention, and **plays no part in the detection of ligand:anti-ligand interactions**.

Turning to Example 5 of Caras et al., the REK7-IgG protein is used to capture and facilitate description of the ligand species specific for REK7. The IgG portion is an active element in this example on at least two levels:

(i) The "scaffold" IgG domain is the means of immobilization of REK7-IgG to a physical support – which is involved in achieving separation of bound (including ligand) and free components from the system of study; and

(ii) Components bind to both REK7 and IgG. Those specific for REK7 are identified by comparison with a parallel affinity purification experiment employing CD4-IgG immobilised on a physical support. Components able to bind to the IgG scaffold domain are common to both experiments –these were observed and were discounted as being of no interest. Components particular to REK7-IgG purification experiment were deemed to be specific for REK7. Thus the IgG scaffold is not non-reactive with the specimen, and strategies to identify and discount its binding partners are inclusive of the present technology.

These experiments demonstrate that REK7-IgG does **not** comprise a system which displays a reactive moiety (REK7) in covalent complex with a non-reactive moiety (IgG) as

noted in the presently claimed invention. The IgG scaffold is active as described in Caras et al., which is unlike the status of scaffold domains in the presently claimed invention.

Further, Applicant notes the following passage from Caras et al. (Col. 20, lines 38-47) concerning the ligand AL-1:

> AL-1 may be used as an immunogen to generate anti-AL-1 antibodies. Such antibodies, which specifically bind to AL-1, are useful as standards in assays for AL-1, such as by labeling purified AL-1 for use as a standard in a radioimmunoassay, enzyme-linked immunoassay, or competitive-type receptor binding assays radioreceptor assay, as well as in affinity purification techniques. Ordinarily, the anti-AL-1 antibody will bind AL-1 with an affinity of at least about 10^6 L/mole, and preferably at least about 10^7 L/mole.

In the presently claimed invention, **the target moieties are not labelled**, which is a precondition of this calibration standard. Also, minimum epitopic features are used in the present invention, whereas Caras et al. describes the use of largely intact protein molecules.

At least in view of the foregoing, it is apparent that Caras et al. does not anticipate the presently claimed invention. It is respectfully noted that "[a]nticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000) (*relying on Electro Med. Sys. S.A. v. Cooper Life Scis.*, 32 USPQ2d 1017, 1019 (Fed Cir. 1994). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

Caras et al. does not adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention, and therefore, Applicant respectfully requests that this rejection be withdrawn.

II. Claim Rejection Under 35 U.S.C. §103

Claim 30 is rejected as being obvious in view of Caras et al. in view of U.S. Patent No. 4,208,479 to Zuk et al. (hereinafter, "Zuk et al."). Applicant respectfully disagrees.

For reasons discussed above, Caras et al. does not teach the presently claimed invention. Zuk et al. does not cure the deficiencies of Caras et al. Turning to Zuk et al., this citation describes an immunoassay capable of calibrating to measure antigen-antibody or ligand-antiligand components quantitatively. The assay relies upon competition between a labelled ligand and the corresponding unlabelled ligand for access to an anti-ligand. In contrast, the presently claimed invention does not rely upon competition between components, nor does it require the preparation of labelled ligand. As such, Zuk et al. describes an invention unlike the presently claimed invention. At most, Zuk et al. describes the composition of a kit to execute their technology. However, as the fundamentals of this invention are unlike that of the presently claimed invention, the description of this kit, even when considered together with the teaching of Caras et al., does not render the presently claimed invention or its delivery in the form of a kit obvious.

As both Caras et al. and Zuk et al. both differ markedly from the presently claimed invention and provide no teaching or direction to one of ordinary skill in the art toward the presently claimed invention, these references fail to render the present invention obvious either alone or in combination. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Additionally, in the event that the present response does not result in receipt of a Notice of Allowance, Applicant respectfully requests the courtesy of a telephone interview to discuss the application in greater detail.

Respectfully submitted,

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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on November 17, 2009.

Betty Lou Rosser